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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,341	06/25/2002	David Michael Shaw	117-385	9257
7590 01/14/2004				
Nixon & Vanderhye 8th Floor 1100 North Glebe Road Arlington, VA 22201-4714		EXAMINER DEVI, SARVAMANGALA J N		
		ART UNIT PAPER NUMBER 1645		

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,341

Applicant(s)

SHAW ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 ~~is~~/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Requirement for Election of Species

- 1) Claims 5-7, 11-15, 21 and 27 have been amended via the amendment filed 10/30/03.
Claims 3-18, 23, 25, 28 and 30 have been amended via the preliminary amendment filed 03/18/02.

Applicants have elected invention I with traverse via the election filed 10/30/03.

Claims 1-30 are under prosecution.

- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hassle, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

- 3) This application contains claims directed to more than one species to be examined. The species identified below do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features.

A. The various pathogenic microorganism species recited in claim 5 as identified below do not share a significant structural element or antigenic make-up: herpes virus, rubella virus, influenza virus, mumps virus, measles virus, poliomyelitis virus, rotavirus, respiratory syncytial virus, *Campylobacter* species, Chlamydial organisms, species of the genus *Cryptosporidium*, cytomegalovirus, human immunodeficiency virus, *Actinomyces* species, *Entamoeba histolytica*, arenaviruses, arboviruses, *Clostridium botulinum*, species of the genus *Candida*, *Vibrio cholera*, *Cryptococcus neoformans*, EHEC strains of *E. coli* 0157:H7, O26:H11, 0111:H8 and O104:H21, ETEC strains of *E. coli*, strains of *E. coli* shown to possess enteroinvasiveness (EIEC), EPEC strains of *E. coli* EAaggEC strains of *E. coli*, DAEC strains of *E. coli*, filoviridae, parvovirus, Filarioidea, *Staphylococcus aureus*, species of the genus *Clostridium perfringens*, *Helicobacter pylori*, Caliciviruses, *Giardia lamblia*, *Neisseria gonorrhoeae*, hantaviruses, hepatitis virus types A, B, C,

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D, and E, *Legionellae* strains, *Mycobacterium leprae*, *Listeria monocytogenes*, species of the genus *Clostridium perfringens*, *Borrelia burgdorferi*, *Pseudomonas pseudomallei*, Epstein Barr virus, *Onchocerca volvulus*, Poxvirus, *Bordetella pertussis*, *Yersinia pestis*, *Coxiella burnettii*, rabies virus, *Treponema pallidum*, *Mycobacterium tuberculosis*, *Salmonella typhi*, a eukaryotic parasite causing malaria, *Pneumocystis pneumonia*, and an agent causing toxoplasmosis.

B. The various pathogen species recited in claim 6 to which protective immune response is against as identified below do not share a significant structural element or antigenic make-up: rotavirus, respiratory syncytial virus, *Mycobacterium tuberculosis*, human immunodeficiency virus, *E. coli*, *Vibrio cholera*, streptococci, and chlamydia.

C. The various heterologous antigen species recited in claim 7 as identified below do not share a significant antigenic make-up: gp160 envelope protein of the HIV virus, a surface glycoprotein of a *Leishmania* parasite, Shiga-like toxin, *Shigella* lipopolysaccharide antigen, *Escherichia coli* fimbrial antigen, a CFA antigen of an enterotoxigenic *Escherichia coli* strain, anthrax toxin, pertussis toxin, and tetanus toxin.

D. The two heterologous antigen species recited in claim 8, human allergen and a tetanus antigen, do not share a significant antigenic make-up.

The various species identified above require separate, non-coextensive and burdensome searches in different classes and/or subclasses. Applicants must make an election of species.

4) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number until January 2004 is (703) 308-9347 and (521) 272-0854 beginning February 2004. A telephone message may be left on the Examiner's voice mail system. The Examiner can be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER